Abstract
The development of the statutory duty of candour in England, from the Francis Report, through the parliamentary journey, up to the developments since the introduction of the regulations.

Explanatory Note
The information contained within this paper was accurate at the date of completion, but may have been overtaken by subsequent policy developments. Nothing in this paper constitutes legal advice or should be used as a replacement for such.
Duty of Candour

1 Introduction

The Care Act 2014 introduced a statutory duty of candour for health and social care providers in England. The details of the duty were subsequently set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The statutory duty of candour:

- Ensure(s) that providers are open and transparent with people who use services and other ‘relevant persons’ (people acting lawfully on their behalf) in relation to care and treatment
- sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology

This paper provides information on the statutory duty of candour and is divided into 6 sections. **Section 2** contains a timeline containing milestones in the development and implementation of the duty. **Section 3** places the statutory of candour in the context of previous calls for enhanced openness and transparency in the NHS and references the

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existing obligations on healthcare professionals. **Section 4** looks at the publication of the Francis Report, the Government’s responses and subsequent reports into patient safety. **Section 5** traces the parliamentary journey of the duty of candour, highlighting relevant committee reports, parliamentary debates and expert contributions. Finally, **section 6** discusses developments since the introduction of the regulations.

## 2 Timeline

<table>
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<tr>
<td>June 2010</td>
<td>Health Secretary establishes public inquiry into failings at Mid-Staffordshire Trust, where between 400-1,200 people died due to poor care over the course of four years.</td>
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<td>January 2011</td>
<td>Conservative-LibDem Coalition introduces the Health and Social Care Bill. An amendment is moved that would have introduced a statutory duty of candour but is disagreed on division.</td>
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<tr>
<td>June 2011</td>
<td>House of Commons Health Committee report on NHS complaints published. Recommended a contractual duty of candour but not a statutory duty.</td>
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<tr>
<td>February 2013</td>
<td>Publication of Francis Report into failings at Mid-Staffordshire Trust calls for a statutory duty of candour for both individuals and organisations.</td>
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<td>March 2013</td>
<td>Government’s <em>initial</em> response (Patients First and Foremost) provided for a duty of Candour to be inserted into the NHS Standard Contract. It also promised a statutory duty of candour on health and care providers to inform people if they believe treatment or care has caused death or serious injury, and to provide an explanation. Report of the Joint Committee on the Draft Care and Support Bill published. The report supported the application of a statutory duty of candour not only to health but that it should extend to all regulated care settings. Government responds and agrees with Committee, but says it will be introduced via secondary legislation, rather than primary.</td>
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<td>May 2013</td>
<td>Care Bill is introduced in the House of Lords. It does not contain a duty of candour clause.</td>
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<td>August 2013</td>
<td>Berwick Review into patient safety published.</td>
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<td>October 2013</td>
<td>Government brings forward amendment introducing statutory duty of candour in the Care Bill.</td>
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<tr>
<td>January 2014</td>
<td>Government publishes <em>detailed</em> response to Francis Report (Hard Truths). It reaffirms the commitment to a statutory duty of candour through the Care Bill along with working with the professional regulators to strengthen the references to candour in professional regulation.</td>
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<td>May 2014</td>
<td>Care Bill receives Royal Assent. Section 81 provides for a Duty of Candour: “Regulations under this section must make provision as to the provision of information in a case where an incident of a specified description affecting a person’s safety occurs in the course of the person being provided with a service.”</td>
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<td>November 2014</td>
<td>The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. These Regulations set out the Fundamental Standards of Care, one of which is Duty of Candour (Regulation 20). The Duty of Candour Regulation applies to NHS providers from the end of November 2014 and to all other social care providers from 1 April 2015.</td>
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## 3 Openness and transparency in the NHS - setting the scene

The perceived need for a statutory duty of candour within the health service dates back a number of years.
In 1987, the then Master of the Rolls, Lord Donaldson, stated: “I personally think that in professional negligence cases, and in particular in medical negligence cases, there is a duty of candour resting on the professional man”\textsuperscript{2}.

A House of Commons Health Select Committee report in 1999 examined “a variety of issues relating to adverse outcomes” and concluded that: “We expect that a professional duty to provide information to relatives of the circumstances surrounding a patient’s death should [suffice], but in case it does not we consider that there should be a statutory duty to provide information”\textsuperscript{3}.

In 2003, the then Chief Medical Officer (Professor Sir Liam Donaldson) set out the case for a statutory duty of candour while recognising the potential chilling effect that the threat of disciplinary action and litigation could have on reporting of adverse incidents\textsuperscript{4}.

**Professional obligations**

Individual healthcare professionals were already obligated to be open and honest with patients when things went wrong. The General Medical Council’s (GMC) *Good Medical Practice Guidance* required doctors to comply with investigations into actual or suspected patient safety events.

Similarly, the Nursing and Midwifery Council’s *The Code* provides similar guidance for its members.

These documents were complemented by the publication of a *professional duty of candour*\textsuperscript{5} in 2014, endorsed by eight regulators of healthcare professionals in the UK.

4 The Mid-Staffordshire scandal, the Francis report and aftermath

If the prospect of a statutory duty of candour had been raised but not acted on, and if healthcare professionals were already obligated even before 2014 to be open and honest about patient safety incidents, then what prompted renewed calls for legislation in this area?

What became known as the Mid Staffordshire scandal involved the deaths of between 400 and 1,200 patients due to poor care between January 2005 and March 2009 at Stafford Hospital. The then healthcare regulator, the Healthcare Commission, became concerned at what it noticed to be unusually high death rates at the hospital and investigated, finding standards of care to be “appalling”\textsuperscript{6}. When the full scale of what

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  \item \textsuperscript{3}https://publications.parliament.uk/pa/cm199899/cmselect/cmhealth/549/54913.htm
  \item \textsuperscript{4}http://webarchive.nationalarchives.gov.uk/20150407084231/http://www.midstaffspublicinquiry.com/report
  \item \textsuperscript{5}http://www.gmc-uk.org/static/documents/content/DoC_guidance_english.pdf
  \item \textsuperscript{6}https://www.theguardian.com/society/2013/feb/06/mid-staffs-hospital-scandal-guide
\end{itemize}
had occurred at the hospital became clear, the incoming coalition government established a public inquiry.

The Francis Report

Robert Francis QC was asked by the Government to chair a public inquiry into the failings at the Mid Staffordshire Trust between 2005-09. The subsequent report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Report, February 2013) made 290 recommendations, one of which was the introduction of a statutory duty of candour for organisations and individuals:

Openness, transparency and candour throughout the system underpinned by statute. Without this a common culture of being open and honest with patients and regulators will not spread. Including:

- A statutory duty to be truthful to patients where harm has or may have been caused;
- Staff to be obliged by statute to make their employers aware of incidents in which harm has been or may have been caused to a patient;
- Trusts have to be open and honest in their quality accounts describing their faults as well as their successes;
- The deliberate obstruction of the performance of these duties and the deliberate deception of patients and the public should be a criminal offence;
- It should be a criminal offence for the directors of Trusts to give deliberately misleading information to the public and the regulators;
- The CQC should be responsible for policing these obligations.

In its initial response published in March 2013, the Government stated that:

The NHS Standard Contract for 2013/14 will include a contractual duty of candour on all providers to be open and honest with patients when things go wrong with penalties for breaching the duty. The rationale for a contractual duty is that individual clinical commissioning groups (as opposed to a single national body) are best placed to examine their own local providers and take action where required. A contractual duty placed upon organisations is also the best approach for encouraging staff to be open and report incidents, and thereby promote a positive safety culture. This is because the onus is on the organisation to create a supportive culture in which people can admit mistakes – a challenging, but nonetheless essential task when it involves a needlessly injured patient or relatives who have been bereaved.

We intend to go further and introduce a statutory duty of candour on health and care providers to inform people if they believe treatment or care has caused death or serious injury, and to provide an explanation. We will need to

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7 Robert Francis had also produced an earlier report into the hospital. This was conducted under the NHS Act and was not part of the public inquiry.
carefully consider the scope of this duty on all providers. We will also work closely with professional regulators to examine what more can be done to encourage professionals to be candid with their patients at all times.

The Berwick Review into Patient Safety

Following the publication of the Francis Report, the Prime Minister asked Professor Don Berwick to carry out a review into patient safety in the NHS. Deviating from the Francis Report, the report concluded that the professional obligations on healthcare professionals to be open and honest negated the need for a statutory duty of candour for individuals. However, in line with the Francis Report, it disagreed with the proposal that every near miss should be reported to patients.

The Government welcomed the overarching findings of the Berwick Report, which was in the public domain by the time the Government published its more detailed response to the Francis Report, *Hard Truths*. In that response, the Government went further in its commitment to a statutory duty of candour by including in the Care Bill a “requirement on the Secretary of State to include a duty of candour in the requirements for registration with the Care Quality Commission” and that the “Department will consult on a draft set of regulations, which also provides the flexibility to be amended or varied over time as the new duty (of candour) is established.” It also stated that the professional duty of candour for healthcare practitioners would be strengthened through “changes to professional guidance and codes.”

The Dalton/Williams Review

In December 2013 Sir David Dalton and Professor Norman Williams were asked by the Department of Health to review the threshold at which a duty of candour could be set to ensure that it was not drawn: “so narrowly that important incidents are excluded, nor so broad that defensive behaviour and excessive bureaucracy grow to excess.” The Review was limited to healthcare.

As part of its work, the review undertook research and heard from a number of stakeholders.

The Review Group commissioned research to look at current thinking regarding national and international patient classification systems. This section summarises some of that report’s findings.

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9 Patients First and Foremost:  


11 Hard Truths:  

12 As above.

13 Paragraph 15:  

Challenges related to classifying patient safety

Section two of the report examined the difficulty in classifying patient safety. It noted the “challenge that the classic concept of an incident leading to one specific outcome is exceptionally rare”, with natural disease progression and errors of omission or commission all potentially playing a contributory factor.

It further highlighted the subjective nature of classifying patient safety incidents, with incidents mainly being classified by junior staff or staff with limited training. Incidents could be reclassified by a patient safety or risk manager in line with that organisation’s definitions: “Whoever classifies them does so by using their individual knowledge, clinical experience, type of expertise, previous experience of a similar incident, personal bias, outcome bias, confirmation bias and hindsight bias. The grading from severe to moderate and low harm is subject to multiple variables and biases…”.

The report stated that patient safety incidents “most often result from a complex interaction of contributory and causal factors”, citing “a complex relationship that exists between incident type (in terms of outcome) and contributing factors:

- The same incident or circumstance may be perceived as an incident or contributing factor, depending on the context, circumstance or outcome
- An incident always has a set of contributing factors
- An incident can be a contributing factor to the origin or development of another incident…”

Findings from Dalton/Williams

The Review recommended that:

A duty of candour requires a culture of candour, and this requires all organisations registered by the CQC to:

- Train and support staff to disclose information about unanticipated events in a patient's care and to apologise when appropriate;
- Improve the levels and accuracy of reporting patient safety incidents so that this information is used as the basis for organisational learning and not for criticism of individuals; and
- Close the ‘audit loop’ by spreading and applying lessons learned into practice and publicly report these15.

On the specific issue of where a threshold should be set, the Review recommended:

Recommendation 2: The duty of candour should apply to all cases of ‘significant harm’. This new composite classification would cover the National Reporting and Learning System categories of ‘moderate’, ‘severe’ and

15 Dalton/Williams Review 2014
The Department accepted “the recommendation that the threshold for the duty of candour in the NHS should include death, severe and moderate harm, as well as prolonged psychological harm”\textsuperscript{17}.

5 Parliamentary journey of the duty of candour

Recent years have witnessed significant legislative activity at Westminster in the field of health and social care and proposals for a statutory duty of candour were made at various times during the accompanying debates. They show the evolution of the government’s thinking which went from opposition to a statutory duty of candour in primary legislation to inclusion of a clause giving effect to such a duty in the Care Act 2014.

2011 Health Committee report on NHS complaints and litigation

A 2011 report on the system for complaints within the NHS addressed the issue of duty of candour. It had heard of instances where the NHS had got things wrong but had failed to offer an explanation.

During oral evidence to the Committee, the Deputy Chief Executive of the NHS and the Chief Executive of the Litigation Authority were asked for their views on a duty of candour:

\textbf{Dr. Wollaston MP}: The NHS Litigation Authority issued a circular to its members encouraging them to apologise when things go wrong. What evidence do you have that more NHS organisations are making timely and appropriate apologies to patients?

\textbf{Stephen Walker}: Probably only less complaints that they are not, is the honest answer to that. The wording of our circular, I think, is the third iteration. We first did that in 1997. I don't manage the NHS, and I have very limited powers beyond managing litigation. What we decided we could do was to remove any legitimate hiding behind the risk of litigation by issuing that circular and expressly saying that it would never be an honest attempt at an explanation; a good faith explanation and apology would never be used as an excuse to avoid liability...

…There are a number of dilemmas, human nature being one of them. No one likes to admit to a mistake, I guess, and professional people are no different to anyone else. There is also the risk of professional regulatory action…There is also what we would call the latent patent problem in that the clinicians are not

\textsuperscript{16} https://www.rcseng.ac.uk/about-the-rcs/government-relations-and-consultation/duty-of-candour-review/

\textsuperscript{17} http://www.ukipg.org.uk/meetings/professional_regulation_working_party/dh_duty_of_candour_consult
always aware that something has gone wrong at the instant it goes wrong. If they are aware and they can remedy the problem immediately, their mindset is not about “I had better do a full explanation and an apology,” but in some cases people leave the hospital and the problem only comes to light many years later. So the opportunity for that instant “I am sorry. What happened was A, B, C” isn't there…

...Things have improved simply, as I say, because we see less complaints about a failure to explain. I am not personally convinced that increasingly rigorous regulation, and even statutory imposition of a duty of candour, is going to make the difference.

A representative from a clinical negligence department at a law firm spoke of the need to implement a cultural shift and without that, a statutory duty of candour may not be helpful.

While mindful of existing candour requirements, such as that contained in the NHS Constitution, the Committee recommended:

...that service agreements between NHS commissioners and their providers should include a contractual duty of candour to the commissioner. A duty of candour to patients from providers should also be part of the terms of authorisation from Monitor, and of licence by the Care Quality Commission.

When commissioning authorities are being authorised by the NHS Commissioning Board they should also be placed under a contractual duty of candour to their populations and to their local Healthwatch organisations18.

The Committee did not however, believe that introducing a statutory duty of candour on the NHS would produce the required cultural shift towards more transparency.

Health and Social Care Bill 2011

The Conservative-Lib Dem Coalition government introduced the Health and Social Care Bill in January 2011. The Bill, which was described as “vast and complex”, was aimed at bringing about far-reaching reorganisation of the NHS. That Bill became law in March 2012.

In February 2012 Baroness Masham of Ilton moved Amendment 17 which would have required the Secretary of State to introduce a statutory duty of candour for all registered healthcare providers and for those providers to be open and transparent with patients when things go wrong. The amendment read as follows:

Figure xx: proposed duty of candour amendment to the Health and Social Care Bill

18 https://publications.parliament.uk/pa/cm201012/cmselect/cmhealth/786/786i.pdf
The Secretary of State’s duty to ensure openness and transparency with patients when things go wrong.

After section 1D of the National Health Service Act 2006 insert—

“1E Duty of candour when things go wrong

The Secretary of State must act with a view to securing that any organisation registered with the Care Quality Commission to provide healthcare is required to take all reasonable steps to ensure that a patient or, in the event of death or incapacity, their next of kin, is fully informed about incidents which occur as a consequence of providing the regulated healthcare to that patient where the incident has resulted in—

(a) any injury to a patient which, in the reasonable opinion of a health care professional, has resulted in—(i) an impairment of the sensory, motor or intellectual functions of the patient which is not likely to be temporary, (ii) changes to the structure of a patient's body, (iii) the patient experiencing prolonged pain or prolonged psychological harm, or (iv) the significant shortening of the life expectancy of the patient; or

(b) any injury to a patient which, in the reasonable opinion of a health care professional, requires treatment by that, or another, health care professional in order to prevent—(i) the death of the patient, or (ii) an injury to the patient which, if left untreated, would lead to one or more of the outcomes mentioned in paragraph (a).

Several Peers spoke in support of the amendment but in response Lord Howe, for the Government, said that while he supported the principle of candour, the CQC was not best placed to administer any new regime:

I remind the House that the Government's preferred position is to place a duty of candour in the NHS standard contracts. We have chosen that route because we feel that it has the best chance of working. The view that we have taken, on the basis of clinical advice, is that the responsibility for ensuring openness needs to rest as close to the front line as possible, rather than being the responsibility of a remote organisation such as the CQC. I would like to focus noble Lords' minds on that point. A contractual duty of candour places the responsibility for requiring openness directly with the organisation looking after patients and with clinician-led commissioners. That is the main reason why we think it will be more effective. By proposing to place a duty of candour in the NHS standard contracts, we are placing the power to hold the NHS to account as close as possible to the people affected by a lack of openness19.

The amendment was disagreed on division.

Joint Committee on Draft Care and Support Bill

In March 2013 the Joint Committee on the published its report on pre-legislative scrutiny of the Draft Care and Support Bill (which was to become the Care Bill). This was one month after the publication of the Francis Report. During oral evidence to the Committee, the Health Secretary Jeremy Hunt was asked for his views on the Francis Report’s recommendation for a duty of candour:

19 https://publications.parliament.uk/pa/ld201213/ldhansrd/text/120213-0001.htm#1202133000100
Q332 Lord Warner: Could I just pursue in this context that we have just been discussing the issue of the Francis proposal for a Duty of Candour? You could argue that a Duty of Candour applied to social care staff would actually help with the Minister’s dilemma about these two conflicting views in the consultation and also with the whole issue of prevention. If they had a Duty of Candour, people who were aware of some of these things might actually blow the whistle a little earlier before too many bad things happen.

Jeremy Hunt: I am very sympathetic to that, and I want to make sure that in our response to Francis we learn the lessons of the NHS and think through what the implications would be for the social care sector. Yesterday the focus was very much on Stafford Hospital and whether other hospitals are at risk of similar awful things happening. Actually if you look at the care stories that worry the public, there have been lots and lots of stories of things happening at care homes.

Norman Lamb: And in people’s own homes in domiciliary care.

Jeremy Hunt: Yes, so I think you are absolutely spot on in asking that question. I cannot really in my own mind see why one would want to introduce something like a Duty of Candour—if that is what we decide to do, and I should add we are very sympathetic to the idea of doing it—that did not apply more broadly than just to the acute sector.

In its report, the Committee stated:

We share the Secretary of State’s view that the application of a statutory duty of candour should not be limited to health but should extend to all regulated care settings. The Care and Support Bill would provide an early opportunity for the Government to legislate on these matters.

Duty of Candour was not raised in any other evidence to the committee, written or oral.

In its response to the Committee’s report, the Government outlined its intended approach to the introduction of a statutory duty of care:

We intend to introduce a statutory duty of candour on health and care providers to inform people if they believe treatment or care has caused death or serious injury, and to provide an explanation. We will need to carefully consider the scope of this duty on all providers. We will also work closely with professional regulators to examine what more can be done to encourage professionals to be candid with their patients at all times. We intend to introduce this duty through secondary legislation, and not through the Care Bill (emphasis added).

Health Committee response to Francis Report

The Health Committee published its response to the Francis Report in September 2013. The Committee recognised the existing duty of candour on health providers as part of the NHS Standard Contract as being “sound”, but believed that the duty was “too narrowly drawn”\(^22\).

As part of its work, the Committee heard evidence from a range of stakeholders, including Robert Francis, who emphasised his argument for a statutory duty of candour alongside the existing obligations placed on individual practitioners:

> In relation to candour to the patient we already have a professional obligation, in their codes of conduct, on the part of doctors and nurses to be honest with patients. What we lack, except by means of guidance, is an obligation on the part of organisations to be honest with patients. First, the organisation must have that responsibility, and, in practical terms, it is the organisation that needs to organise the telling of the patients quite a lot of the time…

> The reason I think it should be a statutory duty is that it is all very well having a contractual obligation to a commissioner, but the reality is that the obligation is to the patient. There needs to be that direct relationship, which needs to be recognised and [. . .] it follows that there will be a remedy involved if that was breached in itself. So there is that duty enforced by a sanction, which means that anyone who gets in the way of that duty deliberately should be subject to criminal sanction\(^23\).

Furthermore, Mr. Francis reiterated the fact that he intended his recommendations to be viewed as part of a package, and that duty of candour should be part of a more general drive towards openness and transparency:

> [T]here is a little bit of confusion often in what we mean by a duty of candour. Conventionally, the discussion has been in terms of candour about honesty to the patient, in telling a patient who has been harmed or might have been harmed by care the truth about that. There is a wider field of candour, which I distinguish by calling it “openness and transparency”, which is about the truth as to more general information concerning the service.

The Health Committee stated that it:

> …remains to be persuaded of the case for the introduction of a statutory duty in addition to existing contractual duties and professional obligations. It is not clear that the proposed duty, the terms of which remain to be defined in

\(^22\) https://publications.parliament.uk/pa/cm201314/cmselect/cmhealth/657/657.pdf  
\(^23\) https://publications.parliament.uk/pa/cm201314/cmselect/cmhealth/657/657.pdf
secondary legislation, will constitute an effective means of achieving the fundamental culture change which is required within the NHS\textsuperscript{24}.

In other oral evidence to the Committee, the Secretary of State for Health, Jeremy Hunt, expanded on the Government's position:

I also want to make the point that we want there to be openness and candour where there is any type of harm. So it is not just about where there is serious injury or death. But when you are talking about statutory duties backed by laws passed in this place, you do have to be careful. As I say, what we are trying to do is to get this tricky balance right so that we do not over-legislate and make the overriding concern in hospitals one about people protecting their legal backsides. We want people to feel that where there is harm, where things go wrong, the normal and right course of action is to be open with everyone about it\textsuperscript{25}.

In response to a question about introducing a new duty of candour on top of existing duties, Mr. Hunt sought to clarify:

Contractual duty of candour applies to everything; it is a standard part of all NHS contracts. What it is saying to people working inside the NHS is, “It is your contractual responsibility as part of working at this hospital”—or in this NHS establishment—“that if you are responsible for patient harm, or if you see patient harm, you tell someone about it.” That is part of people’s contracts. What we are saying is that there will be a statutory duty on organisations to make sure that people who are harmed, or their families, are told, where this has led to serious harm or death. It is a higher grade, if you like, for the organisation. We have also said that there will be criminal liability on organisations if they deliberately supply misleading information about things like mortality rates. We are raising the bar in terms of the potential sanctions at organisation level, but we are going to wait until Don Berwick completes his review before we decide whether that should apply to people at an individual level as well\textsuperscript{26}.

**The Care Bill 2013**

The Care Bill was introduced in the House of Lords on 10 May 2013. The Bill as introduced contained “provisions relating to adult care and support, care standards, health education and research”\textsuperscript{27}. Although there was no clause relating to duty of candour in the original Bill, Members of both Houses sought to introduce amendments to place a statutory duty of candour on the face of the Bill.

\textsuperscript{24} As above.

\textsuperscript{25} https://publications.parliament.uk/pa/cm201314/cmselect/cmhealth/657/657.pdf

\textsuperscript{26} https://publications.parliament.uk/pa/cm201314/cmselect/cmhealth/657/657.pdf

A duty of candour clause was introduced at the Lords Report stage on 16 October 2013:

**Amendment 140 Lord Howe for the Government**

“Duty of candour

In section 20 of the Health and Social Care Act 2008 (regulation of regulated activities), after subsection (5) insert—

“(5A) Regulations under this section must make provision as to the provision of information in a case where an incident of a specified description affecting a person’s safety occurs in the course of the person being provided with a service.”

Speaking to the amendment, Lord Howe explained that it struck a balance between leaving the duty of candour to regulations or placing it explicitly in the Bill:

The Government’s approach is to introduce this duty as a requirement for registration with the CQC. In Committee, noble Lords tabled amendments that sought to place the duty of candour in the Bill. The amendment that I am presenting today seeks to strike a balance; I make no apology for that, since it allows us to have the best of both worlds. The amendment tabled in my name makes it clear that the Government must introduce such a regulation. It does not present the Government with a choice; rather, it imposes a crystal clear obligation on the Government to put such a regulation in place.

In reply, Lord Hunt, who had tabled a more detailed amendment, welcomed the amendment:

It is very important; we welcome the duty of candour being placed in the Bill. The amendment is less detailed than my own and will rely on regulations, as the noble Earl, Lord Howe, has said. The important thing is to get this in the Bill.

**Shadow Health Minister’s amendment**

In January 2014 the Shadow Minister for Health moved an amendment that would have set out in more detail in the Bill what the duty of candour required of service providers, rather than leaving this to regulations:

**Amendment 139 – Shadow Minister for Health**

(The duty of candour specified in regulations made under this section shall require—

(a) healthcare service providers who believe or suspect that treatment or care provided by their service has caused or contributed to death or serious injury to that patient to inform that patient, their representative or other authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient or other person mentioned may reasonably request, and

(b) registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are
There was significant discussion on the amendment in the Public Bill Committee, with the key points summarised below:

- The Shadow Minister for Health welcomed Clause 80 but regretted that the detail of the duty was not to be set out in the Bill. He argued that this would have “provided an opportunity for a full, frank and transparent debate between patient groups, care providers, the Department, trade unions, the royal colleges and others”. Speaking about the omission of a statutory obligation on individuals, he stated that its inclusion “would also assist in the development of better communication…between medical professionals and patients and better communication between medical professionals themselves”. He recognised the argument that medical professional groups had put forward, namely that existing obligations of candour in professional guidelines obviate the need for legislation. Nevertheless, the Shadow Minister for Health said that if professional guidelines already exist to ensure candour, then there should be no issue with placing it on a statutory footing.

- In response, the Minister of State for Health pointed out that “It is important that we take the time to get the details right. Putting the threshold for the duty in regulations, rather than primary legislation, enables us to do that”.

The amendment was withdrawn when the Shadow Minister was reassured that the Government was committed to openness in both health and social care and would consult on regulations once it had received the report of the duty of candour working group.28

**Candour Commissioner**

Proposed new Clause 33, which had cross-bench support, sought to establish a ‘Candour Commissioner’ who would have had responsibility to:

(a) protect and promote a culture of candour and disclosure in the public interest in the health and care services sector,

(b) provide or arrange confidential advice and support for persons working in the health and social care sector considering making a disclosure in the public interest

(c) provide or arrange advice and support for persons in the sector who have made such a disclosure, and

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28 [https://www.theyworkforyou.com/pbc/2013-14/Care_Bill/10-0_2014-01-23a.7_0](https://www.theyworkforyou.com/pbc/2013-14/Care_Bill/10-0_2014-01-23a.7_0)
(d) monitor the treatment, employment and re-employment of persons mentioned in paragraph (c) within the sector29.

New Clause 33 was not moved.

**Written evidence**

The following organisations referenced duty of candour in their written evidence on the Care Bill:

- **Royal College of Surgeons**: only to reference the fact that its President had been asked to assess whether regulations created by the clause should extend a duty of candour to cover moderate harm, as well as death or serious injury.

- **Chartered Society of Physiotherapy**: supported the Duty of Candour clause and asked that “Committee opposes the opposition amendment to apply the Duty to Candour to health and care professionals, rather than working with professional bodies to incorporate into professional standards. In our view this amendment works against the goal of making health and care organisations places where staff can be encouraged to learn and raise issues of concern”30.

- **British Medical Association**: the BMA supported the duty of candour and was pleased that “the Government has ruled out introducing an individual statutory duty of candour [1] and believe it is unnecessary. Doctors already have a duty to be open and honest with patients about their care through Good Medical Practice, [2] the professional code governing their fitness to practise. This requires immediate action where a patient has suffered harm or distress, and an apology and full disclosure about what has happened. It also requires doctors to be honest in their communications with patients at all times, to comply with their employer’s patient safety systems and respond promptly to any concerns about or risks to patient safety…The BMA opposes amendment 139 which seeks to introduce an individual duty of candour which is unnecessary and could have unintended negative consequences”31.

- **Ken Lownds**: (former member of campaign group Cure the NHS) “my belief is that a duty of candour anyway exists in the codes of conduct of doctors and nurses. Rather than have a general Duty of Candour as envisaged here I believe any duty additional to what already exists in the codes of conduct should be built into a "mandatory incident reporting system"32.

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31 [https://publications.parliament.uk/pa/cm201314/cmpublic/care/memo/cb24.htm](https://publications.parliament.uk/pa/cm201314/cmpublic/care/memo/cb24.htm)
32 [https://publications.parliament.uk/pa/cm201314/cmpublic/care/memo/cb34.htm](https://publications.parliament.uk/pa/cm201314/cmpublic/care/memo/cb34.htm)
The Care Act 2014 received Royal Assent in May 2014, with section 80 stating:

**81 Duty of candour**

In section 20 of the Health and Social Care Act 2008 (regulation of regulated activities), after subsection (5) insert—

“(5A) Regulations under this section must make provision as to the provision of information in a case where an incident of a specified description affecting a person’s safety occurs in the course of the person being provided with a service.”

**Regulations**

In March 2014 the Department of Health consulted on proposals to introduce a new CQC registration regulation. Its analysis of responses noted that:

A significant majority of those who responded to (the question of whether respondents agreed with the requirements to be placed on service providers) were in favour of the requirements to be placed on service providers if harm above the threshold has arisen. It was seen as fitting with current best practice and congruent with Being Open guidance and the requirements of the Duty of Candour outlined in the NHS Standard Contract and mirrors good practice already in place in some healthcare organisations. Broadly, those against the requirements were concerned that the requirements were too onerous.

There were a number of common themes in the comments, including the importance of advocacy and support and the need for better guidance and for training. Some respondents also thought that the regulations should include provision to ensure that lessons are learnt by providers; that information should be shared with the service user in terms that are relevant and comprehensible and that apologies should not be given if no-one is at fault. There was also a suggestion that the regulations should require provider organisations to take appropriate action against individuals who prevent the organisation complying with the Duty of Candour.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 relates to duty of candour and is reproduced at Appendix 1. What follows is a summary of the main provisions of the Regulation:

1. Registered persons must act in an open and transparent way with a patient or someone acting on their behalf when a notifiable safety incident has occurred.

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2. A notifiable safety incident is defined as an unintended or unexpected incident that could or has resulted in:

- **Death**

- **Serious harm**: this means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user’s illness or underlying condition.

- **Moderate harm**: this means harm that requires a moderate increase in treatment, and significant, but not permanent, harm, for example a “moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)

- **Prolonged psychological harm**: this means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

3. In accordance with the legal duty of candour, the registered provider must:

- As soon as practically possible notify the relevant person of the incident
- Offer an apology
- Provide reasonable support following the incident, including helping to find out the reasons for the accident

The notification must:

- Be given in person
- Provide an accurate and full account of the incident to the best of the registered person’s understanding
- Advise the relevant person of what further enquiries into the incident the registered person believes are necessary; any results of the further enquires must be passed on to the patient or relevant contact
- Include an apology
- Be recorded in writing; a written copy must be given to the registered person

The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015 extended the duty to all providers from 1 April 2015.

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6 Developments since the Care Act

The duty of candour has been in force since November 2014 for NHS bodies and since April 2015 for all other relevant organisations.

NHS Resolution

The National Health Service Litigation Authority (whose functions are now encompassed by NHS Resolution) “is a not-for-profit Special Health Authority that provides indemnity cover for legal claims against the NHS, supports learning from claims and provides other legal and professional services for its members”\(^{35}\). The NHSLA has published information on the duty of candour and is clear that 'saying sorry' will not be taken as an admission of liability on its part\(^{36}\) and references the Compensation Act 2006 as stating that ‘An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of a statutory duty’.

AvMA report

AvMA published a report which analysed 90 CQC Inspection Reports compiled between 1 January 2015 and 31 December 2015. It found inconsistency in CQC inspections with 7% of the reports making no reference to duty of candour and 19% making only what AvMA termed a ‘superficial’ reference\(^{37}\). In response to the report, CQC said that in the first year since the introduction of the duty, CQC had been focused on Trusts’ awareness of the new regime and that it had since worked with AvMA to refine its approach to inspections\(^{38}\).

Parliamentary and Health Service Ombudsman

In December 2015 the Parliamentary and Health Service Ombudsman (PHSO) published *A review into the quality of NHS complaints investigations where serious or avoidable harm has been alleged*\(^{39}\).

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\(^{39}\)[https://www.ombudsman.org.uk/sites/default/files/A_review_into_the_quality_of_NHS_complaints_investigations_where_serious_or_avoidable_harm_has Been alleged.pdf](https://www.ombudsman.org.uk/sites/default/files/A_review_into_the_quality_of_NHS_complaints_investigations_where_serious_or_avoidable_harm_has_Been_alleged.pdf)
The review found that although Trusts told the PHSO that they reported more incidents since the duty was introduced:

- There is no national, accredited training programme to support investigators and/or complaints staff in their role. Cultural issues can often be a barrier to getting to the heart of why something has happened.
- Common reasons cited during our visits to trusts included a lack of respect; not being provided with protected time to investigate, and the lack of an open and honest culture despite the introduction of the duty of candour in November 2014.

**Establishment of Healthcare Safety Investigation Branch**

A report from the Public Administration Select Committee on investigating clinical complaints in the NHS recommended the establishment of an Independent Patient Safety Service whose “sole objective...should be to prevent incidents and to improve patient safety, and not to apportion blame or liability”. One of the core functions of the body should be to:

- offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals.

In its response, the Government committed to establish such a body and set up an Expert Advisory Group to report on the role, purpose and operation of the new body. Subsequently, on 1 April 2016, the Secretary of State for Health issued Directions establishing the Healthcare Safety Investigation Branch and setting out basic functions. The Directions emphasised the importance of the HSIB creating a ‘no-blame’ culture which would allow for candid discussions and contributions.

The Public Administration and Constitutional Affairs Committee noted that:

Evidence received by the Committee was very supportive of the proposed ‘safe space’ principle, with the Royal College of Physicians of Edinburgh arguing that if it could be “truly create[d]” it would represent the “single biggest improvement in terms of creating openness and transparency” as “many clinicians remain hugely concerned about personal risk to themselves in a very challenging environment.”

There was disagreement among members of the EAG on the safe space principle, due to concerns that it could lead to the withholding of information from patients and families. The final report of the EAG therefore highlighted the need for healthcare providers to be able to discuss openly and without fear of recrimination events that

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40 As above.
41 [https://publications.parliament.uk/pa/cm201617/cmselect/cmpubadm/94/94.pdf](https://publications.parliament.uk/pa/cm201617/cmselect/cmpubadm/94/94.pdf)
involved honest mistakes. However, it also stated the importance of complying with the
duty of candour, providing patients and their carers with all information relevant to their
care.

The Chief Executive of AvMA was a member of the EAG and in a subsequent blog post
was critical of how the Secretary of State’s Directions deviated from the EAG
recommendations. Specifically, the EAG report recommended that all relevant
information relating to a patient’s safety ‘must’ be released. This was changed in the
Directions to the Chief Investigator ‘may, when requested’ disclose such information to
the extent that the Chief Investigator judges it to be consistent with the safe space
principle42.

Public Administration Select Committee

In May 2016 the Public Administration and Constitutional Affairs Committee published
its report PHSO review: Quality of NHS complaints investigations. Addressing the duty
of candour, the Committee put to the Minister for Care Quality that there was a lack of
a culture of candour in the NHS. In response, the Minister recognised that there was
still work to be done:

If you see the way the Secretary of State approaches this about candour on
never events, his openness about avoidable mortality, not uncontroversial I
would posit at the moment, all of this suggests that the leadership from the top
at an official and at a political level is there. But has that yet permeated
through the entire organisation? No43.

In response, the Committee stated:

The Committee welcomes the Minister for Care Quality’s admission that more
work must be done to fully implement the statutory Duty of Candour. We urge
the Department of Health to press ahead with training staff across all NHS
organisations in applying this principle. There must be a greater focus across
the system on dealing with patients and their families and carers with
compassion and respect when their case is the subject of a clinical
investigation. HSIB must embody this in its own investigations, but
responsibility for delivering this change across the whole healthcare system
sits with NHS Improvement and NHS England more widely44.

42 https://www.avma.org.uk/policy-campaigns/the-avma-blog/the-healthcare-safety-investigation-branch-glass-half-full-or-half-
empty/
43 https://publications.parliament.uk/pa/cm201617/cmselect/cmpubadm/94/94.pdf
44 https://publications.parliament.uk/pa/cm201617/cmselect/cmpubadm/94/94.pdf
Appendix 1: Regulation 20 Duty of Candour

20.
1. Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.

2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, a registered person must—
   a. notify the relevant person that the incident has occurred in accordance with paragraph (3), and
   b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.

3. The notification to be given under paragraph (2)(a) must—
   a. be given in person by one or more representatives of the registered person,
   b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
   c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
   d. include an apology, and
   e. be recorded in a written record which is kept securely by the registered person.

4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
   a. the information provided under paragraph (3)(b),
   b. details of any enquiries to be undertaken in accordance with paragraph (3)(c),
   c. the results of any further enquiries into the incident, and
   d. an apology.

5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person—
   a. paragraphs (2) to (4) are not to apply, and
   b. a written record is to be kept of attempts to contact or to speak to the relevant person.

6. The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).

7. In this regulation—
   “apology” means an expression of sorrow or regret in respect of a notifiable safety incident; “moderate harm” means—
   a. harm that requires a moderate increase in treatment, and
   b. significant, but not permanent, harm.
   “moderate increase in treatment” means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);
   “notifiable safety incident” has the meaning given in paragraphs (8) and (9);
   “prolonged pain” means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
   “prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
   “relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—
   a. on the death of the service user,
b. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or

c. where the service user is 16 or over and lacks capacity in relation to the matter;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—

a. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or

b. severe harm, moderate harm or prolonged psychological harm to the service user.

9. In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—

a. appears to have resulted in—
   i. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
   ii. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
   iii. changes to the structure of the service user's body,
   iv. the service user experiencing prolonged pain or prolonged psychological harm, or
   v. the shortening of the life expectancy of the service user; or

b. requires treatment by a health care professional in order to prevent—
   i. the death of the service user, or
   ii. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).